IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

THE WASHINGTON UNIVERSITY,)
Plaintiff,)
v.) C.A. No. 13-2091 (GMS)
WISCONSIN ALUMNI RESEARCH FOUNDATION,	REDACTED PUBLIC VERSION
Defendant.)

DEFENDANT'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S COMPLAINT

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Mary B. Graham (#2256) Derek J. Fahnestock (#4705) 1201 N. Market Street P.O. Box 1347

Wilmington, DE 19899-1347 (302) 658-9200

mgraham@mnat.com dfahnestock@mnat.com

Attorneys for Wisconsin Alumni Research

Foundation

OF COUNSEL:

Robert F. Shaffer Michael A. Morin Shana K. Cyr, Ph.D. FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP 901 New York Avenue, NW Washington, DC 20001-4413 (202) 408-4000

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I. NATURE AND STAGE OF THE PROCEEDINGS

This case by The Washington University ("WashU") against Wisconsin Alumni Research Foundation ("WARF") purportedly arises out of a 1995 Inter-Institutional Agreement ("the 1995 Agreement") between the parties. (D.I. 1, Ex. A.)¹ WashU served the Complaint on December 31, 2013 (*see* D.I. 7), and by Order of this Court on January 10, 2014, the time for WARF to respond is February 20, 2014 (*see* D.I. 9). WARF now moves pursuant to Federal Rule of Civil Procedure 12(b)(6) for the Court to dismiss all Counts of WashU's Complaint, because the Complaint fails to state any claim for which relief can be granted.

II. SUMMARY OF ARGUMENT

- 1. This case involves a 1995 contract (D.I. 1, Ex. A) between two sophisticated parties that governs their relationship with respect to the invention claimed in U.S. Patent No. 5,597,815 ("the '815 patent").
- 2. The '815 patent is directed to a method of using a compound known as paricalcitol to treat renal osteodystrophy while avoiding an unwanted effect known as hyperphosphatemia. Paricalcitol is the active ingredient in AbbVie Inc.'s ("AbbVie") Zemplar® products, which are approved and marketed for the treatment of secondary hyperparathyroidism in chronic kidney disease patients.
- 3. WARF is the sole owner of the dominating U.S. Patent No. 5,587,497 ("the '497 compound patent"), which claims the paricalcitol compound itself; of U.S. Patent No. 5,246,925 ("the '925 secondary hyperparathyroidism patent"), which claims using

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relating to WARF's	paricalcitol compound.
4.	WARF and WashU co-own the '815 patent.
5.	
	But WashU has now decided that it wants more, and has brought suit as a
way out of the partie	s' original bargain as set forth in their 1995 Agreement.
6.	
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this brief refe	References to "Abbott" in

paricalcitol to treat secondary hyperparathyroidism; and of dozens of other patent families

WashU l	as
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not pointed to any specific provision of the contract that WARF has allegedly breached or presented any well-pleaded factual allegations plausibly establishing that WARF breached the contract. Count I should be dismissed.

7. WashU's breach of contract claim is also barred by the applicable six-year statute of limitations. Even if WashU had sufficiently pleaded factual allegations plausibly establishing breach of the 1995 Agreement—which it did not—the breach of contract claim would have accrued and the statute of limitations would have begun in

See CLL Assocs. Ltd. P'ship

- v. Arrowhead Pac. Corp., 497 N.W.2d 115, 117 (Wis. 1993) ("[I]n an action for breach of contract, the cause of action accrues and the statute of limitations begins to run from the moment the breach occurs. This is true whether or not the facts of the breach are known by the party having the right to the action." (citations omitted)). Count I should be dismissed for this reason alone.³
- 8. Faced with a contract that has not been breached and, further, a breach of contract claim that is barred by the statute of limitations, WashU relies on tort claims—breach of implied covenant of good faith and fair dealing (Count II) and breach of fiduciary duty (Count III)—to circumvent the parties' original bargain as set forth in their 1995 Agreement.

 But WashU has not presented any well-pleaded factual allegations plausibly establishing that it is

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entitled to relief for these claims. WashU has not pointed to anything indicating that WARF had any obligations or duties outside of those expressly established in the contract.

Moreover, WashU's reliance on the 1995 Agreement as the basis for its tort claims is telling and notably is impermissible as a matter of law. *See McDonald v. Century 21 Real Estate Corp.*, 390 N.W.2d 68, 70 n.3 (Wis. Ct. App. 1986) ("[T]here must be a duty *existing independently of the performance of the contract* for a cause of action in tort to exist." (alteration in original) (quoting *Landwehr v. Citizens Trust Co.*, 329 N.W.2d 411, 414 (Wis. 1983))).

Counts II and III should thus be dismissed.

- 9. Moreover, WashU's tort claims are barred by the applicable three-year statute of limitations. Even if WashU had sufficiently pleaded factual allegations plausibly establishing its tort claims—which it did not—the claims would have accrued and the statute of limitations would have begun by
- See CLL Assocs., 497 N.W.2d at 117 ("Tort claims accrue and the statute of limitations begins to run on the date that the injured party discovers, or with reasonable diligence should have discovered, the tortious injury, whichever occurs first." (citations omitted)).

 Counts II and III should be dismissed for this reason alone.
- 10. WashU's claim for an equitable accounting (Count IV) should also be dismissed. WashU has not presented any well-pleaded factual allegations plausibly establishing that it is entitled to such relief. WARF is not holding any money or property that belongs to

WashU and there is no fiduciary duty or special ground for invoking equity jurisdiction.

Count IV should therefore be

dismissed.

III. STATEMENT OF FACTS

A. The Parties and the Invention

WARF is a not-for-profit organization that has served as the designated technology transfer organization for UW since 1925. WashU is a corporation and major scientific institution founded in 1853 that now includes over 3,000 instructional faculty members and nearly 12,000 full-time undergraduate and graduate students. (D.I. 1 at ¶ 1.)

One of the prominent UW inventors that WARF has worked with over the years is Dr. Hector DeLuca, the father of vitamin D. After identifying the naturally occurring active form of vitamin D in the 1970s, Dr. DeLuca and members of his laboratory spent decades exploring, developing, and testing various vitamin D analogs for biological activity. In the late 1980s, Dr. DeLuca and his UW collaborators invented the vitamin D analog known as paricalcitol, as well as its use in treating a condition known as secondary hyperparathyroidism in chronic kidney disease patients. With WARF's help, the inventors obtained a family of patents, including a patent directed to the paricalcitol compound (the '497 compound patent) and a patent directed to using paricalcitol to treat secondary hyperparathyroidism (the '925 secondary hyperparathyroidism patent). The '497 and '925 patents were assigned to WARF, as were dozens of other patent families relating to paricalcitol.

Around 1995, Dr. DeLuca collaborated with Dr. Eduardo Slatopolsky, a medical doctor and professor of medicine at WashU, to further study WARF's paricalcitol compound. Drs. DeLuca and Slatopolsky discovered that paricalcitol could be used for treating patients while avoiding an unwanted effect known as hyperphosphatemia. In 1997, through WARF's efforts, the discovery was afforded patent protection in the form of the '815 patent.

B. The 1995 Agreement

On November 1, 1995 (i.e., after Dr. DeLuca and Dr. Slatopolsky's discovery but
before the '815 patent issued), WARF and WashU entered into the 1995 Agreement (D.I. 1, Ex.
A) to govern their relationship with respect to the hyperphosphatemia invention.



	A 1 (12012)	177
	And until 2012, more than a decade later, Wa	
those paymer	nts without further inquiry, and without giving WARF any indication	on that WashU
had additiona	al questions or concerns.	
С.	The Zemplar Patents and Hatch-Waxman Litigations	

WARF and Abbott have asserted the '815 patent in Hatch-Waxman litigations against various generic manufacturers seeking to market generic paricalcitol capsules and injections.⁵ In some of these cases (i.e., against Hikma, Sun, and Banner), the '815 patent was the only patent asserted, but that is only because the generic manufacturers agreed that the dominating '497 compound patent, which is still in force, is valid and would be infringed by a generic paricalcitol product.⁶ IV. **ARGUMENT** But WashU has now decided that it wants more. As discussed below, each of WashU's claims should be

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See AbbVie Inc. v. Hikma Pharm. Co., No. 1:13-cv-1557-GMS (D. Del., filed Sept. 13, 2013); AbbVie Inc. v. Dr. Reddy's Labs. Ltd., No. 1:13-cv-1012-GMS (D. Del., filed June 5, 2013); AbbVie Inc. v. Sun Pharm. Indus. Ltd., No. 1:13-cv-0138-GMS (D. Del., filed Jan. 24, 2013); AbbVie Inc. v. Banner Pharmacaps, Inc., No. 1:12-cv-1228-GMS (D. Del., filed Sept. 28, 2012); Abbott Labs. v. Sandoz Inc., No. 1:12-cv-0836-GMS (D. Del., filed June 29, 2012); Abbott Labs. v. Agila Specialties Private Ltd., No. 1:12-cv-0520-GMS (D. Del., filed Apr. 25, 2012); Abbott Labs. v. Hospira Inc., No. 1:11-cv-0648-GMS (consolidated) (D. Del., filed July 21, 2011).

dismissed because the Complaint does not contain well-pleaded factual allegations that—even if taken as true—"plausibly give rise to an entitlement to relief." *See Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009); *id.* at 678 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007))); Fed. R. Civ. P. 12(b)(6). Moreover, at least Counts I-III are barred by the applicable statute of limitations.

A. Count I for Breach of Contract Should Be Dismissed

WashU's breach of contract claim (Count I) does not plead factual allegations sufficient to plausibly give rise to an entitlement to relief, even if taken as true. *See Ashcroft*, 556 U.S. at 679. WashU has not pointed to any specific provision of the contract that WARF has allegedly breached, or presented any well-pleaded factual allegations plausibly establishing that WARF breached the contract. And, indeed, there has been no breach.

	Count I should thus
be dismissed.	

WashU's breach of contract claim is also barred by the applicable six-year statute of limitations. *See* Wis. Stat. § 893.43 (2013) (providing a six-year statute of limitations for

"[a]n action upon any contract, obligation or liability, express or implied"). Even if WashU had sufficiently pleaded factual allegations plausibly establishing breach of the 1995 Agreement—which it did not—the breach of contract claim would have accrued and the statute of limitations would have begun in

See CLL Assocs., 497 N.W.2d at 117 ("[I]n an action for breach of contract, the cause of action accrues and the statute of limitations begins to run from the moment the breach occurs. This is true whether or not the facts of the breach are known by the party having the right to the action." (citations omitted)). Count I should be dismissed for this reason alone.

B. Counts II and III for Tort Claims Should Be Dismissed

Faced with a contract that has not been breached, and further, a breach of contract claim that is barred by the statute of limitations, WashU relies on tort claims—breach of implied covenant of good faith and fair dealing (Count II) and breach of fiduciary duty (Count III)—as a means of circumventing the parties' original bargain as set forth in their 1995 Agreement. But WashU has not presented any well-pleaded factual allegations plausibly giving rise to an entitlement to relief for these tort claims, even if taken as true. *See Ashcroft*, 556 U.S. at 679. WashU has not pointed to anything indicating that WARF had any obligations or duties outside of those expressly established in the contract.

The parties are—and were at the time they entered into the contract—sophisticated entities. They did not expressly create a fiduciary relationship in the contract

Without an express provision, there is no contractual fiduciary duty. *See Jackson v. McKay-Davis Funeral Home, Inc.*, 830 F. Supp. 2d 635, 648 (E.D. Wis. 2011) ("A contract, standing alone, is insufficient to create a fiduciary duty." (citing *Merrill Lynch, Pierce, Fenner & Smith v. Boeck*, 377 N.W.2d 605, 609 (Wis. 1985); *Prod. Credit Ass'n of Lancaster v. Croft*, 423 N.W.2d 544, 546 (Wis. Ct. App. 1988))).

Even if there were a fiduciary duty—which there was not—WashU has not sufficiently pleaded a breach of such duty and WARF's conduct cannot be said to have risen to the level of an intentional tort. *See Zastrow v. Journal Commc'ns, Inc.*, 718 N.W.2d 51, 62 (Wis. 2006) (stating that breach of fiduciary duty is an intentional tort and that "negligent conduct does not rise to the level of a breach of fiduciary duty"). WashU does not explain or provide facts to support its conclusory statement that "WARF acted deliberately and in disregard of [WashU's] rights" (D.I. 1 at ¶ 64), or even set forth what rights WashU is referring to.

Moreover, Counts II and III fail as a matter of law. WashU's reliance on the 1995 Agreement as the basis for its tort claims is telling and notably is a not a practice permitted under the law. *See McDonald*, 390 N.W.2d at 70 n.3 ("[T]here must be a duty *existing independently of the performance of the contract* for a cause of action in tort to exist." (alteration in original) (quoting *Landwehr*, 329 N.W.2d at 414)); *RxUSA*, *Inc. v. Capital Returns*, *Inc.*, No. 06-C-790, 2007 WL 2712958, at *11, 2007 U.S. Dist. LEXIS 68223, at *30-34 (E.D. Wis. Sept. 14, 2007) (dismissing a breach of fiduciary duty claim where the complaint "merely restate[d] [the defendant's] contractual duty"); *Northgate Motors*, *Inc. v. Gen. Motors Corp.*, 111 F. Supp. 2d 1071, 1082 (E.D. Wis. 2000) (stating that the implied covenant of good faith and fair dealing "imposes a relatively limited obligation on the parties and is not a basis for creating rights not expressly included in the contract"); *Wis. Natural Gas Co. v. Gabe's Constr. Co.*, 582 N.W.2d

118, 121 (Wis. Ct. App. 1998) (stating that the implied covenant of good faith and fair dealing cannot override a contract's express terms). Counts II and III should thus be dismissed.

In addition, WashU's tort claims are barred by the applicable three-year statute of limitations. *See* Wis. Stat. § 893.57 (2013) (providing a three-year statute of limitations for intentional tort claims); *Lewis v. Paul Revere Life Ins. Co.*, 80 F. Supp. 2d 978, 1004 (E.D. Wis. 2000) ("The applicable statute of limitations [for breach of fiduciary duty claims] is that for intentional torts, Wis. Stat. Ann. § 893.57 (West 1997)." (citing *Warmka v. Hartland Cicero Mut. Ins. Co.*, 400 N.W.2d 923 (Wis. 1987))). Even if WashU's claims were not legally deficient and insufficiently pleaded, the claims would have accrued and the statute of limitations would have begun by

See CLL Assocs.,

497 N.W.2d at 117 ("Tort claims accrue and the statute of limitations begins to run on the date that the injured party discovers, or with reasonable diligence should have discovered, the tortious injury, whichever occurs first." (citations omitted)). Counts II and III should be dismissed for this reason alone.

C. Count IV for Equitable Accounting Should Be Dismissed

WashU has not presented any well-pleaded factual allegations that plausibly give rise to an entitlement for relief for an equitable accounting claim, even if taken as true. *See Ashcroft*, 556 U.S. at 679. WARF is not holding any money or property that belongs to WashU and there is no fiduciary duty or special ground for invoking equity jurisdiction. WashU alleges that it *may* be unable to determine what it should have been paid under the 1995 Agreement without additional information (D.I. 1 at ¶ 66), but this is not sufficient under the law to support an equitable accounting claim:

Accounting is a claim in equity available when a plaintiff needs to compel an accounting of his money or property held by a defendant. A court requires more than a mere statement by a party that he does not know the status of his account, however. It requires both a complete inadequacy of legal remedies and a special ground to invoke equity jurisdiction. "These special grounds of equity jurisdiction may be stated, generally, to be the need of a discovery, the complicated character of the accounts, and the existence of a fiduciary or trust relation."

RxUSA, 2007 WL 2712958, at *12, 2007 U.S. Dist. LEXIS 68223, at *35-36 (citations omitted) (quoting *Walter Diehnelt, Inc. v. Root*, 198 N.W. 388, 389 (Wis. 1924)).

To the extent that any of WashU's other claims go forward—which they should not—WashU would be able to gather relevant information through the discovery process such that the equitable accounting claim should be dismissed. *Id.* at 2007 WL 2712958, at *12, 2007 U.S. Dist. LEXIS 68223, at *36 ("The need for a party to pursue an equitable accounting claim is generally unnecessary in light of modern discovery rules." (citing *Didion Milling, Inc. v. Agro Distrib., L.L.C.*, No. 05-C-227, 2007 WL 702808, at *11, 2007 U.S. Dist. LEXIS 15071, at *30-31 (E.D. Wis. Mar. 2, 2007))). Conversely, if WashU's claims are dismissed, WashU has no need for the requested information and, thus, its equitable accounting claim should be dismissed.

Count IV should be dismissed.

V. CONCLUSION

For the reasons stated herein, WARF respectfully requests that the Court grant WARF's motion and dismiss with prejudice WashU's breach of contract, breach of implied

covenant of good faith and fair dealing, breach of fiduciary duty, and equitable accounting claims under Rule 12(b)(6).

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

Mary B. Graham (#2256)
Derek J. Fahnestock (#4705)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
dfahnestock@mnat.com
Attorneys for Wisconsin Alumni
Research Foundation

OF COUNSEL:

Michael A. Morin Robert F. Shaffer Shana K. Cyr, Ph.D. FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP 901 New York Avenue, NW Washington, DC 20001-4413 (202) 408-4000

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